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Atty Dkt: 263742001000

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on SEPT. 14, 1995
9/14/95 *Jean P. Prie*
Date Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

BRUCE ROSER et al.

Serial No.: 08/486,043

Filed: June 7, 1995

For:

METHODS FOR STABLY
INCORPORATING SUBSTANCES
WITHIN DRY, FOAMED GLASS
MATRICES AND COMPOSITIONS
OBTAINED THEREBY

Examiner: Unknown

Group Art Unit: Unassigned

1802

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR § 1.97

Assistant Commissioner
for Patents
Washington, D.C. 20231

Dear Sir:

The information listed below, which may be material to the examination of the above-identified application, was disclosed throughout the application as originally filed. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

Pikal, "Freeze-drying of proteins. Process, formulation, and stability" ACS Symposium Series, Formulation and Delivery of Proteins and Peptides J.L. Cleland et al., eds., (1994) 567:120-133.

Carpenter et al., "Interactions of stabilizers with proteins during freezing and drying" ACS Symposium Series, Formulation and Delivery of Proteins and Peptides J.L. Cleland et al., eds., (1994) 567:134-147.

Crowe et al., "Are freezing and dehydration similar stress vectors? A comparison of modes of interaction of stabilizing solutes with biomolecules" Cryobiol. (1990) 27:219-231.

U.S. Patent No. 4,891,319 to Roser (01/02/90).

U.S. Patent No. 5,149,653 to Roser (09/22/92).

U.S. Patent No. 5,026,566 to Roser (06/25/91).

Blakeley et al., "Dry instant blood typing plate for bedside use" Lancet (1990) 336:854-855.

Roser, "Trehalose, a new approach to premium dried foods" Trends in Food Sci. and Tech. (July 1991) pp. 166-169.

Colaco et al., "Trehalose stabilisation of biological molecules" Biotechnol. Internat. (1992) pp. 345-350.

Roser, "Trehalose drying: A novel replacement for freeze-drying" BioPharm. (1991) 4:47-53.

Colaco et al., "Extraordinary stability of enzymes dried in trehalose: Simplified molecular biology" Bio/Tech. (1992) 10:1007-1011.

Roser et al., "A sweeter way to fresher food" New Scientist (1993) 138:25-28.

Crowe, et al., "Stabilization of biological membranes at low water activities" (1983) Cryobiol. 20:346¹-356.

Argall et al., "The use of trehalose-stabilized lyophilized methanol dehydrogenase from *Hyphomicrobium* X for the detection of methanol" Biochem. Mol. Biol. Int. (1993) 30:491-497.

Hottiger et al., "The role of trehalose synthesis for the acquisition of thermotolerance in yeast. II. Physiological concentrations of trehalose increase the thermal stability of proteins *in vitro*" Eur. J. Biochem. (1994) 219:187-193.

Loomis et al., "Anhydrobiosis in nematodes: Inhibition of the Browning reaction of reducing sugars with dry proteins" J. Exp. Zool. (1979) 208:355-360.

Sanchez et al., Recombinant system for overexpression of cholera toxin B subunit in *Vibrio cholerae* as a basis for vaccine development" Proc. Natl. Acad. Sci. USA (1989) 86:481-485.

Takahashi et al., "Induction of CD8⁺ cytotoxic T cells by immunization with purified HIV-1 envelope protein in ISCOMs" Nature (1990) 344:873-875.

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The references above are summarized throughout the application as originally filed. The summaries contain what the undersigned believes to be the salient aspects of the cited references. They are not intended to be a comprehensive statement of the relevance of the references to the subject invention.

This Information Disclosure Statement is submitted before receipt of the first Office Action on Merits. Therefore, the applicants believe that no fee is due. However, the Commissioner is hereby authorized to charge any fees which may be required by this paper to Deposit Account Number 03-1952.

Applicants would appreciate the Examiner's initialling and returning the Form PTO-1449, indicating that the references have indeed been considered and made of record herein.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or

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(iv) the above information constitutes prior art to the
subject invention.

Respectfully submitted,

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